The LMK Advantage

Times are changing and now, more than ever, you need document management tools that help you make smarter decisions and gain the competitive advantage.

LMK can help.

TMF Management & Process Planning

We are flexible and offer a full range of document management services - from SOP development through archive. Our team members are TMF experts and have extensive knowledge in clinical trial drug development and the TMF. As part of your study team,we provide guidance as subject matter experts ensuring TMF compliance to guarantee quality deliverables..

LMK TMF experts will work with you throughout the life cycle of your product to effectively plan, collect, and manage your clinical trial documents on an ongoing basis. Our team performs TMF QC and remediation across Functional Lines, ensures TMF appropriateness and accuracy, and provides additional TMF support during an audit inspection

TMF Planning	Develop SOPs that ensure the System of Record for all content is properly documented. Implement the TMF (RM) based on your SOPs, not just the RM. Review the TMF RM by zone to determine which documents are applicable, create a master reference document for use by the entire company, ensure a complete and thorough master list of possible content to file in the TMF.
TMF University	Our unique training program is designed for novice learners to experts covering a range of TMF topics in 16 modules: from document recognition training to TMF quality control processes. The TMF University can provide the foundational knowledge required to understand the TMF.
TMF Maintenance	Ensure documentation filed meet quality criteria throughout the study once the master list is built. Collect, file, and store your paper documents. Establish a process for collecting documents from Functional Lines, clinical sites, and CROs (if applicable) from study start through study completion
TMF Quality Control	Ensure that the TMF as a whole is complete, accurate, and inspection ready at all times. Implement a TMF QC process that can be followed by all Functional Lines regardless of the type of content that is or has been filed.
TMF Closeout	Perform final TMF QC and remediation ensuring that all discrepancies have been resolved, and the TMF is properly closed and archived (paper, eTMF system or hybrid).

QUALITY DRIVEN

Ensuring TMF quality is the single most important deliverable of a clinical trial. Given the current attention to the TMF, regulatory agencies can show up at any time to review the content. Don't be caught off guard. Make sure your trial is ready by having the leaders in TMF management at LMK provide our proven TMF QC processes.

DEDICATED ELITE TMF REVIEW TEAM

The Elite TMF Review Team (ETRT) is a dedicated team who performs TMF QC and remediation (if needed) for risk-based or 100% of the content within the TMF. The ETRT has experience in paper, electronic, and hybrid TMFs and is available to assist you onsite or remotely. With expertise in clinical trials and TMF management, the ETRT reviews your TMF content in a timely manner using an established process and tool to perform TMF QC that highlights gaps and discrepancies within the TMF.

By utilizing LMK's ETRT, you benefit from increased process efficiency and TMF compliance - saving you time and reducing your costs while increasing the quality of your TMF:

Identifies and documents true discrepancies and potential gaps within the TMF. Resolves discrepancies rather than generating a long list of queries for your team to resolve.

Ensures your TMF is inspection ready at all times throughout the study through routine TMF QC - providing you with another level of validation.

Reduce costs and expedites timelines through "effecient" TMF content QC and remediation.

TMF REFERENCE MODEL

You haven't adapted the TMF Reference Model yet? Our team can review your SOPs to determine which document types from the TMF Reference Model are applicable to your company.

TMF MIGRATION

We are an eTMF agnostic company and are fullly trained in all of the major eTMF technologies. If you need to streamline your TMF process and want to have your TMF content in one electronic repository, we can help. Our experienced resources will migrate your TMF content quickly and efficiently ensuring instant access to your trial content.

RESOURCES

Is a flexible resourcing model important to you? We can provide short and long term resources to support your TMF activities: from TMF management through TMF QC and remediation. Depending on your needs, our resources can be onsite or virtual. We can make our flexible model work for you!